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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,482	11/19/2003	Naveen Arora	2761-0169P	3751
2292 7590 04/01/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
FORD, VANESSA L				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
04/01/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/715,482

**Applicant(s)**

ARORA ET AL.

**Examiner**

VANESSA L. FORD

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/9/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**FINAL ACTION**

1. This Office Action is responsive to Applicant's response filed December 9, 2009. Claims 2, 9-35 and 38 have been canceled. Claims 1, 3-8 and 36-37 are under examination.

***Declaration***

2. The *In re Katz* under 37 CFR 1.132 filed December 9, 2009 is sufficient to overcome the rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(a) based upon Applicants' explanation that the publication "Effects of Various stabilizing agents on *Imperata cylindrica* grass Pollen Allergen Extract", *Clinical and Experimental Allergy*, 2003, vol. 33, pages 65-71 is Applicants' own work.

***Rejection Withdrawn***

3. In view of Applicants' remarks and submission of *In re Katz* declaration, the rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(a), pages 2-5, paragraph 2 of the previous Office action is withdrawn.

***Rejection Maintained***

4. The rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(b) as anticipated by Bijli et al (*Journal of Immunological Methods* 260 (Feb. 2002, 91-96) is maintained for the reasons set forth on pages 9-12, paragraph 5 of the Final Office Action.

The rejection is reiterated below:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 93, Figures 1 (a)-(c)). Bijli et al teach a protein that is stable at room temperature (page 92). Claims limitations such as “hydrophobic in nature”, “resistant to trypsin”, “has no proteolytic activity”, “inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner” and “is devoid of any carbohydrate moiety”, wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin” “wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin”, “wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity” and “wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity” would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein ). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

**Applicant's Arguments**

Applicant urges that they have pointed out the differences between the presently claimed invention and the invention disclosed in Bijli, 2002. Applicant urges that the amino-terminus of the protein in the Bijli 2002 is blocked and cannot be determined by Edman degradation. Applicant urges that the Examiner believes that the protein of Bijli 2002 and the protein of Verma et al, 2000 (of record) are the same.

Applicant urges that the protein of the present invention has a "free" amino-terminus. Applicant points to the Declaration of Naveen Arora filed February 6, 2006 and suggest that this declaration established plain differences between the present invention and the proteins cited in the prior art references. Applicant urges that there is substantial evidence made of record that disclose the difference between the protein of the prior art and the presently claimed protein.

Applicant urges that the Examiner is asserting inherency of various claimed biochemical activities recited in the claims. Applicant urges that the Examiner's statement of *"Products of identical chemical composition cannot have mutually exclusive properties."* a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present" betrays a complete lack of understanding of protein biochemistry. Applicant urges that the 3-dimenisional shape of the protein can be different depending on how the protein is treated. Applicant urges that the protein of Bijli 2002 is separated by SDS-PAGE in which the protein unfolds and unfolds the 3-diminisional structure of a protein. Applicant urges that it is well known in that art that "native" proteins are normally folded. Applicant urges that contrary to the Examiner's assertion of inherency the "protein isolated by SDS-PAGE would probably not have the biological activity of inhibiting proteolytic cleavage of protein antigen (PA) of *Bacillus anthracis* in a dose dependent manner".

Examiner's Response to Applicant's Arguments

Applicant's arguments filed December 9, 2009 have been fully considered but they are not persuasive.

Bijli et al, 2002 teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Bijli et al, 2002 teach an isolated protein because the protein is analyzed by SDS-PAGE. It is noteworthy to point out that Bijli et al, 2002 makes reference to a 67 kDa protein from *Imperata cylindrica*. See page 93 of Bijli et al 2002.

The declaration of Naveen Arora under 37 CFR 1.132 filed February 6, 2006 is insufficient to overcome the rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(b) as anticipated by Bijli et al (*Journal of Immunological Methods* 260 (Feb. 2002, 91-96)). There is no evidence in Bijli et al, 2002 that suggests that the amino-terminus of the disclosed 67 kDa protein is blocked.

Applicant has not established the protein of the prior art and the claimed protein are patentably distinct. The SDS-PAGE analysis used to isolate the protein on a gel does not prevent the protein from having the claimed biological activities as claimed. In fact, the instant specification teaches that SDS-PAGE analysis was performed on the claimed protein. See Figure 4 of the instant specification. Applicant has not submitted any evidence to point to the differences between the claimed protein and the protein of the prior art. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities as the claimed protein. Applicant has not established that the 3-dimensional conformation of the

protein of the prior art would not allow this protein to possess the claimed biological activities.

To address Applicant's comment regarding function it should be noted that the protein of the prior art is the same as the protein of the claimed invention. The MPEP 2112.01 states that " *Products of identical chemical composition can not have mutually exclusive properties.*" *a chemical composition and its properties are inseparable.* Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty."). Again, Applicant has not shown that the protein of the prior art differs from the claimed protein such that the protein of the prior art would not be able to possess the same biological activities as claimed.

Bijli et al, 2002 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

#### ***Status of Claims***

5. No claims allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/

Primary Examiner, Art Unit 1645

March 24, 2010